

Meeting Minutes: FDA and ANS

Company: ANS
Meeting Date: May 18, 2000 2-3:00 pm
Location: 9200 Corporate Blvd., Rockville, MD 20850 Room 230 V
Type of Meeting: Reclassification of Totally Implantable Spinal Cord Stimulators
Background: ANS has filed petition to reclassify devices from Class III to Class II

FDA Attendees:

Celia Witten, M.D. PhD, Div. Dir, DGRND
Russ Pagano, Ph.D., Branch Chief, REDB
Janet Scudiero, Exec. Sec., Neuro Panel
Kristen Bowsher, Ph.D., Reviewer, REDB
Joseph Sheehan, Chief, Regs, OHIP
Natalie Tudor, Consumer Safety Officer, DGRND

ANS Attendees;

Chris Chavez, President
Drew Johnson, Dir., Regulatory Affairs
Larry R. Pilot, LLP, McKenna and Cuneo

Type of Meeting: To determine status of ANS petition to FDA to reclassify implantable spinal cord Stimulators from Class III to Class II.

Sponsor presented overview of market with Medtronic-80%, ANS-7% and Cyberonics-10%.
Sponsor reviewed meeting with FDA Feb 1999 stating RF and IPG equivalent, except one with battery inside and other outside.

FDA: Reclassification petition was an option for the sponsor; devices are similar but not necessarily equivalent. FDA's position is the February letter is still valid; FDA has enough information but has not made a decision on reclassification to Class II. Regarding special controls, FDA does not have new "special controls" at this time. As FDA goes through the decision process the company may be asked for more information but the next step is to continue to review.

FDA has to publish Panel recommendation and get comments. Since there was a split Panel (5-1) there are questions and issues.

Even though under review FDA cannot share with sponsor- where we are in the review process but appreciates the sponsor telling FDA where they are.

Since FDA laid out options a year ago; implantable spinal cord stimulators have already been determined Class III, therefore, do not see "de nova" as a regulatory route for sponsor.

Sponsor: Sponsor requests suggestions for company to have a process to market an IPG. An option of company is to pursue litigation that FDA is not in compliance with Act. Sponsor stated that statute has a time course and now in Day-360-400.

FDA: FDA could advise sponsor, instead of looking at 510(k) and PMA, as to what things go into a Class II 510(k) since sponsor will have to address either way. Sponsor's plan to address additional risks is good.

FDA asked sponsor to relook at petition and revisit special controls and these can be added. If sponsor is comfortable going 510(k) route--if reclassified--the entire class of products (devices of same generic type) would automatically become predicates.

Sponsor: Sponsor is trying to find the least burdensome path. Plans are to launch device in Europe the third quarter of this year. Sponsor would be prepared to do a 510(k) by June 15th, only missing FDA's special controls.

Summary:

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FDA will take back the list of what sponsor can provide and see if there are any other things sponsor can add. Sponsor will communicate with Dr. Bowsher after FDA looks at list.

In the process of reclassification FDA does not see that sponsor's submitting a 510(k) now would be a good choice.

Process has been an open process with Panel /dockets

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